Attachment 15
510(k) Summary for the
Cutera Optional Pulsed Light Hand Piece Family

I. General Information

Submitter: Cutera Inc.
3240 Bayshore Boulevard
Brisbane, CA 94005

Contact Person: Kathy Maynor

Summary Preparation Date: December 29, 2004

II. Names

Device Names: Cutera Optional Pulsed Light Hand Piece Family

Primary Classification Name: Laser Powered Surgical Instrument (and Accessories)

III. Predicate Devices

- Starlux/Estelux pulsed light hand pieces manufactured by Palomar (K033549, K040081, K020941)
- Profile BBL manufactured by Sciton (K032460)
- PRIMA Pulsed Light Therapy System manufactured by CoolTouch.

IV. Product Description

The pulsed light delivery hand pieces are comprised of four main components:

- an "umbilical" cable and connector, that is permanently attached to the hand piece body and is semi-permanently attached to the console system (detachable by positive action from the user) that houses:
- electrical cables (to support the thermoelectric cooler associated with the chilled hand piece tip, to provide power and a trigger source to the xenon flash lamp, to provide detector signals and to connect a memory device that identifies the hand piece);
- a supply and return water line (to remove the heat generated by the flash lamp and thermoelectric cooler);
- the hand piece internals described above; and
- the hand piece housing the internals and connecting to the umbilical.

These hand pieces are accessories to be used on previously cleared Cutera console systems where the 510(k) permitted use of pulsed light (a.k.a. flash lamp) hand pieces.

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V. Indications for Use

The Cutera Optional Pulsed Light Hand Piece Family is indicated for use in the surgical, aesthetic and cosmetic applications requiring selective photothermolysis in the medical specialties of general and plastic surgery and dermatology.

The Cutera Optional Pulsed Light Hand Piece Family is intended for the treatment of:

- Tattoos;
- Benign pigmented lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles);
- Cutaneous lesions including warts, scars and striae;
- Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, roasacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
- Psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis;
- Removal of unwanted hair from all skin types, and to effect stable long-term, or permanent, hair reduction; and
- Mild to moderate inflammatory acne vulgaris.

VI. Rationale for Substantial Equivalence

The Cutera Optional Pulsed Light Hand Piece Family shares the same indications for use, similar design features (including wavelength, light generation medium, power supply, cooling and control system), functional features (including power output, spot size, repetition rate, energy and fluence), and is therefore substantially equivalent to the above legally marketed predicate devices.

VII. Safety and Effectiveness Information

The new **indications for use** are based upon the indications for use for predicate pulsed light device systems.

Technologically, the Cutera Optional Pulsed Light Hand Piece Family is substantially equivalent to the listed predicate devices. Therefore the risks and benefits for the Cutera Optional Pulsed Light Hand Piece Family are comparable to the predicate devices.

We therefore believe that there are no new questions of safety or effectiveness raised by the introduction of this device.

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VIII. Conclusion

The Cutera Optional Pulsed Light Hand Piece Family was found to be substantially equivalent to the currently marketed predicate devices. The Cutera Optional Pulsed Light Hand Piece Family shares similar indications for use, design features, and similar functional features as, and thus is substantially equivalent to, the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2005

Ms. Kathy Maynor
Vice President of Regulatory/Quality
Cutera, Inc.
3240 Bayshore Boulevard
Brisbane, California 94005

Re: K050047
Trade/Device Name: Optional Pulsed Light Hand Piece Family
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 31, 2004
Received: January 10, 2005

Dear Ms. Maynor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K050047

Device Name: **Cutera Optional Pulsed Light Hand Piece Family**

Indications For Use:

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- Psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis;
- Removal of unwanted hair from all skin types, and to effect stable long-term, or permanent, hair reduction; and
- Mild to moderate inflammatory acne vulgaris.

Prescription Use ___√___	AND/OR	Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D)		(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050047